



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,786	01/26/2004	Thomas William Deveney	SAR 15036	9752
58882	7590	10/11/2006	EXAMINER	
LOWENSTEIN SANDLER P.C. 65 LIVINGSTON AVENUE ROSELAND, NJ 07068			ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/764,786	<b>Applicant(s)</b> DEVENEY ET AL.	
	<b>Examiner</b> James W. Rogers, Ph.D.	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

All previous rejections in the office action dated 05/04/2006 have been withdrawn.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by DePrince et al. (US 4,898,733, included in applicants IDS).

DePrince teaches a device for the controlled release of a beneficial agent (includes drugs) and the method to produce it, the device can comprise two body fluid-contacting layers which allow a controlled release of the beneficial agent contained within each fluid contacting layer and in the non-body fluid contacting drug containing region, the fluid contact layers can be molded to opposite sides of the non-body fluid contacting layer, the device can further comprise an impermeable coating or sleeve (the sleeve can be comprised of cellulose acetate) with open ends as in figure 2. See abstract, fig. 2, col 2 lin 41-45 and lin 65-col 4 lin 30, col 5 lin 18-23 and lin 56-68 and col 6 lin 37-48.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over DePrince et al. (US 4,898,733, included in applicants IDS) in view of Guo et al. (US 2002/0102307 A1, included in applicants IDS).

DePrince is disclosed above. DePrince discloses that the beneficial agent can be contained in the body fluid-contacting portion of the device thus meeting the limitation of a dose unit of drug disposed adjacent to both the 1<sup>st</sup> and 2<sup>nd</sup> end of the sleeve outside of the drug retaining region. DePrince also discloses that the non-body fluid contacting region can be coated.

DePrince does not disclose the use of any type of sealing surface or caps on the controlled release device.

Gua discloses a sustained release drug delivery device with a first cap having an open center and being received by the first end of a sleeve and abuts a marginal region of a controlled release layer and a second cap which has an open center and being received by the first end of a sleeve and abuts a marginal region of a controlled release layer. See [0057] and fig 4. The examiner considered a cap to also encompass the limitation of a sealing surface. Guo also discloses that the devices have applicability in providing a controlled and sustained release of agents effective in obtaining a desired local or systemic or physiological or pharmacological effect. See [0068]-[0073].

Therefore from both disclosures it would have been obvious to the skilled artisan that one could use more than one type of drug in these devices and it would have been obvious that the drugs could be contained in different regions or zones in the devices.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because DePrince discloses all of applicants claimed invention except for the use of any type of sealing surface or caps on the controlled release device while Guo disclosed that it was already well known in the art to use caps on controlled release devices with holes in it to better control the release of a pharmaceutically active agent. The motivation to combine the above documents would be a controlled deliver device comprised of a sleeve open on both ends and capped on the ends with a controlled release layer on either side of the sleeve adjacent to the sleeve ends and in the center a drug reservoir, the release of the drug contained in the reservoir being controlled by the release layers and the hole(s) in the caps. The advantage of such a controlled release

Art Unit: 1618

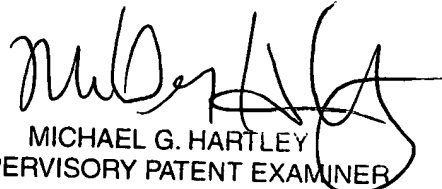
device would be the control of the drug could be modified by both the controlled release layers and the end caps, thereby effecting essentially a zero order release. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER